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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,975	01/10/2002	John Jairo Damarati	10121/02101	3029

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NEW YORK, NY 10038

EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,975

Applicant(s)

DAMARATI, JOHN JAIRO

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 10, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 11, 18 and 20 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 10, 12-14, 19, and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-6, 9, 11, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storz-Irion ("Storz" et al. WO 01/80746 A1) in view of Thompson 5,662,654. Regarding Claims 1, 3, and 18, Storz discloses a suturing tool comprising: (from figure 1) a first catheter (1) capable of being sealed into the working channel of an endoscope, a plurality of anchoring members (6), a driving member (7) extending through the first catheter (1) to a proximal end thereto wherein advancing the driving member distally in the first catheter advances the anchoring members distally through the first catheter to drive a distal-most one of the anchoring member out of the first catheter, and a length of suture extending between the suture receiving proximal ends of the anchor members (this occurs once the anchors are placed in the body). As figure 1 shows, the circular anchors do not resemble the anchors of the applicant's invention. However, page 7, lines 22-27 states that the anchor member can be any suitable body, which fix-position the thread in an opening in a locking or positive manner. Thompson discloses a suturing device having anchoring members including a shaft extending from the tissue penetrating distal tip to the suture receiving

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proximal end and a gripping arm (figure 25, 141) having a gripping and insertion configuration. This anchor is superior to that of Storz because this anchor provides an enhanced anchoring means, the barbs, which act to prevent the anchor from being removed. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the anchors of the Storz device with the anchors of the Thompson device because the barbs of Thompson provide an enhanced anchoring means (141).

2. Regarding claim 2, the driving member of Storz is designed to press an anchor into a tissue. The composition of the material of the driving member is not disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the Storz driving member of metal since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. The driving member contains a piston. Since the piston could obviously be made of metal, and metal materials are inherently flexible, the piston is inherently flexible.
3. Regarding claim 4, the anchors shown in Storz appear to be floating on top of one another. Some force must exist to push the anchors into the lower triangle. This force is not disclosed. It would have been logical to use gravity to push the anchors towards the lower triangle to prepare the anchors to be inserted into the skin. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the force of gravity to pull the anchors towards the bottom of the catheter so they can be inserted into the skin. Since the combined device uses gravity to position

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the anchors, the anchors would be inherently be pressed next to one another by the force of gravity.

4. Regarding claim 5, the suture would be fixed to the distal most one of the anchoring members that are inserted.
5. Regarding claim 9, the outer casing of the Storz device (1) is considered the first catheter. The second catheter is element 8, which is inside the first catheter.
6. Regarding claim 11, element 10 is part of the driving mechanism, element 10 is a knot holding section. Element 16 is a suture cutting surface.
7. Regarding Claims 3, 6, 18 and 20, the extending means (the spring force/memory of members 41/141 [see Fig. 3; Column 21 lines 21-24]) deploys the gripping arms (41/141) from the insertion configuration to the deployed configuration. The gripping arms will exert contact pressure (141) on anchoring member while they are lodged in contact pressure mechanism (170)—a hollowed out area in anchoring member (140).

Allowable Subject Matter

8. Claims 7, 8, 10, 12-14, 19, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:
9. Regarding claim 3, the combined Storz device doesn't disclose a catheter sized to maintain the anchor in the insertion configuration.
10. Regarding claims 7 and 8, multiple hinges on the catheters are not disclosed by Storz.

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11. Regarding claim 10, the driving mechanism is inside a different catheter than the anchors.
12. Regarding claim 12, the driving member doesn't have a lumen with a suture within it.
13. Regarding claim 13, after the distal most anchor is deployed, the second catheter cannot couple with that anchor.
14. Regarding claim 14, Storz does not disclose a suture holding pin in combination with claim 11.
15. Claims 15-17 are allowed. The following is a statement of reasons for the indication of allowable subject matter: claims 15-17, the Storz device does not disclose three concentric catheters interalia the limitations of claim 15.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory

period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

17. Applicant's arguments filed 12/10/2004 have been fully considered but they are not persuasive. WO 01/80746 A1 to Storz-Irion et al. and U.S. Patent No. 5,662,654 to Thompson are analogous pieces of prior art, both intended for the application of fasteners with suture to bone tissue and other kinds of tissue.
18. Regarding Applicant's argument that the modified Storz-Irion device does not meet the preamble to claims 1 and 18 [REMARKS, page 4 middle paragraph], Examiner disagrees. Applicant has not breathed life into the preamble, limiting the invention to *only* endoscopically suturing the inside of a stomach. Applicant has only set forth suturing "an internal organ of a patient." The language Applicant uses *does not exclude other intended uses* than suturing the inside of a stomach.
19. Regarding Applicant's contention that Storz-Irion does not disclose "a length of suture extending between the suture receiving proximal ends of the anchoring members" Examiner disagrees and refers Applicant to Figure 3 of the Storz-Irion reference. The suture (5) *very clearly* extends *through each anchoring* member (6)—through both the distal and proximal ends of each anchoring member (6). Therefore, the Storz-Irion reference meets the limitation "a length of suture extending between the suture receiving proximal ends of the anchor members."
20. Regarding Applicant's contention that Thompson shows only bone anchors with blunt tips [REMARKS, page 4 first paragraph], Examiner refers Applicant to Figure 3

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of U.S. Patent No. 5,662,654 to Thompson. Tip (44) is sharp and capable of piercing tissue, including bone tissue or flesh tissue [Column 12, lines 36-52]. Additionally, *all* of Thompson's clips are meant to be *driven into an anchoring position in bone tissue*, and therefore meet Applicant's claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
January 28, 2005


ANHTUAN T. NGUYEN
PRIMARY EXAMINER
